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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>20 April 2010</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-24,26,27 and 29</u> is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-24,26,27 and 29</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a)☐ All   b)☐ Some *   c)☐ None of:

         1.☐ Certified copies of the priority documents have been received.

         2.☐ Certified copies of the priority documents have been received in Application No. _____.

         3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08)
     Paper No(s)/Mail Date <u>02/26/2010, 04/20/2010</u>.

4)☐ Interview Summary (PTO-413)
     Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____ .

DETAILED ACTION

1.   The following office action is a **Final Office Action** in response to communications received on 04/20/2010. Claims 1, 13, 20, 22, 24, 26 and 29 have been amended. Claims 25, 28 and 30 have been canceled. Therefore, claims 1-24, 26-27 and 29 are pending in this application.

Response to Amendment

2.   Applicant's amendment to claim 26 is sufficient to overcome the claim objections set forth in the previous office action. Accordingly, the Examiner withdraws the objection.

Applicant's amendment to claim 20 is sufficient to overcome the 35 U.S.C. 112 second paragraph rejection set forth in the previous office action. Accordingly, the Examiner withdraws this rejection.

Claim objections

3.   Claims 1-12 are objected due to the following informalities. The term "through a interconnecting member" in line 23 of claim 1 is believed to be a typographical error for "through an interconnecting member". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4.   The claimed limitations "means for communication between said control unit and said interface unit" and "means for generating control signals" as recited in both claims 20 and 26; claim elements "means for simultaneously simulating handling of a number of nested instruments", "means for handling and processing said input", "means for controlling movements of a number of serially arranged and interconnected carriages",

"means for simulating an effect of a first instrument inserted into a second instrument"

as recited in claim 20; and the claim element "means for receiving three-dimensional

information" as recited in claim 26 are means (or step) plus function limitations that

invoke 35 U.S.C. 112, sixth paragraph.

Accordingly, the "means for generating signals", "means for handling and

processing said input", appear to correspond to the computer (PC) described in the

specification; the "means for simultaneously simulating handling of a number of nested

instruments" appears to correspond to the interface unit described in the specification;

the "means for controlling movements of a number of serially arranged and

interconnected carriages" appears to correspond to the speed regulator and distance

regulator described in the specification; and the "means for receiving three-dimensional

information" appears to correspond to the scanning process such as MRI described in

the specification.

In addition, with regard to the claimed limitations, "means for communication

between said control unit and said interface unit" and "means for simulating an effect of

a first instrument inserted into a second instrument", Applicant has indicated in the

record (according to the response filed on 02/04/2010) that the "means for

communication between said control unit and said interface unit" corresponds to the

digitized communication instruction set described in the specification (e.g. Para.0032),

and the "means for simulating an effect of a first instrument inserted into a second

instrument", is best realized as a computer program and that computer program may

include a first instruction set for simulating handling of a number of simulated

instruments simultaneously interfaced by the interface unit (Para.0013).

Claim Rejections - 35 USC § 103

5.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

●   Claims 1-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Anderson 2002/0168618 in view of Alexander 6,929,481 and further

in view of Messner 5,987,960.

Regarding claim 1, Anderson discloses the following claimed limitations, an

interventional procedure simulation system, having a control unit and an interface unit

(FIG 4), said control unit communicating with said interface unit to simulate handling of

a number of real nested instruments simultaneously interfaced by said interface unit

(Para.0018) and, said instruments being arranged to move and rotate independently of

each other and said movements and rotations being propagated to the other

instruments (Para.0018 and Para.0035), said control unit including an instruction set

comprising a first instruction set for handling and processing an input from a user based

on said input, generating a second instruction set for controlling said interface

(Para.0125, lines 7-14), a first data set comprising characteristics for said instruments

(Para.0084, lines 10-16 and Para.0125, lines 17-19), a second data set comprising data

on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a third instruction set for generating control signals relating to an interaction between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21).

Anderson further discloses, a fifth instruction set for calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacitg (Para.0071), said instruction set being configured to calculate movements of said first instrument propagated to the second instrument (FIG 5B and Para.0120).

Anderson does not explicitly disclose, a fourth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit, each carriage comprising: members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander discloses an interface device and method in medical procedure simulation that teaches, a fourth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit (see col.22, lines 5-18 and also FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps for implementing a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 2, said interventional procedure is at least one of a diagnostic, a cardiovascular or endovascular simulation system (see Abstract lines 5-8 and Para.0012, lines 1-4),

Regarding claim 3, a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, affect a shape of an instrument simulated and displayed (Para.0020 and Para.0149, lines 6-12),

Regarding claim 4, each instrument collisions with simulated surrounding calculations are executed by said control unit, which affects the shape and position of said instrument in said simulated body part (Para.0205 and Para.0206, lines 1-8),

Regarding claim 5, wherein an instrument is a distal part of a tool or an end of a tool (Para.0036, lines 1-10),

Regarding claim 6, wherein different instrument types can be used comprising at least one of balloons, stems, electrodes, wires, catheters, and distal protection(Para.0018, lines 3-8),

Regarding claim 7, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claims 8 and 9, the properties of said instruments further describe interaction with at least one of surrounding geometry, visual properties, stiffness, and shape; and wherein simulated properties of said instrument are altered in real-time (Para.0034, lines 3-13),

Regarding claim 10, the system comprises a model used for rendering objects depending on properties to be displayed and a collision model for computing collisions between the simulated instrument and body part (Para.0200 and Para.0205),

Regarding claim 11, a model of said body or part of said body part is a three-dimensional data obtained through a body scanning (Para.0021, lines 1-3 and Para.0128, lines 1-4),

Regarding claim 12, the instrument movements and rotations interact simulated with other instruments (Para.0035 and Para.0157, lines 9-13).

Regarding claim 13, Anderson discloses the following claimed limitations: a method for simulating an interventional procedure (Para.0032, lines 1-8), comprising the

steps of providing a control unit and an interface unit (FIG 4), said control unit

communicating with said interface unit to simulate handling of a number of nested real

instruments simultaneously interfaced by said interface unit (Para.0018) and that each

nested tool is configured to be moved and rotated independently of the other and said

movements and rotations are propagated to other instruments (Para.0035), providing a

first instruction set for handling and processing input from a user, generating a second

instruction set based on said input, for controlling said interface (Para.0125, lines 7-14),

retrieving information on said instrument comprising a first data set comprising

characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), providing a

second data set comprising data on a body part to be simulated (Para.0033, lines 1-6,

and Para.0124, lines 5-9), and generating control signals relating to interaction between

said instrument and a surrounding geometry by a third instruction set (see Para.0034,

lines 3-10 and Para.0125, lines 19-21).

Anderson further discloses, calculating an effect of a first instrument inserted into

a second instrument in a nested manner (Para.0035 and Para.0036) each instrument

having properties, being at least one of a natural shape, stiffness, length, diameters and

radioopacity (Para.0071) and calculating movements of said first instrument propagated

to the second instrument (FIG 5B and Para.0120).

Anderson does not explicitly disclose, said interface unit including an instruction

set for controlling movements of a number of serially arranged and interconnected

carriages, corresponding to movements of said instruments in said interface device

each carriage comprising members to receive and lock at least one of the instruments,

and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, an interface unit including an instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit/device (col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (see e.g. col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

Alexander in an alternative embodiment further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 14, changing instrument simulated and displayed based on a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, effect a shape of an instrument simulated and displayed (Para.0020, lines 7-16 and Para.0034, lines 3-13),

Regarding claim 15, wherein an instrument is a distal part of a tool or an end of a tool (Para.0036, lines 1-10),

Regarding claim 16, wherein different instrument types can be used comprising at least one of balloons, stents, electrodes, wires catheters, and distal protection (Para.0018, lines 3-8),

Regarding claim 17, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claim 18, wherein the properties of said instruments further describe interaction with at least one of surrounding geometry, visual properties, stiffness, and shape etc (Para.0035 and Para.0157, lines 9-13),

Regarding claim 19, wherein simulated properties of said instruments are altered in real-time (Para.0020, lines 7-14 and Para.0036, lines 6-16).

Regarding claim 20, Alexander discloses the following claimed limitations: a system for an interventional procedure simulation, said system having a control unit and an interface unit (FIG 4), the system further comprising means for communication between said control unit and said interface unit, means for simultaneously simulating handling of a number of nested instruments interface by said interface unit, each said instruments being, independently movable and rotatable (Para.0018; Para.0035 and Para.0157, lines 9-12), an interface member configured to receive input from a user including an instruction set, means for handling and processing said input (Para.0020, lines 7-14 and Para.0022), means for controlling said interface (Para.0022, lines 1-9), a

first database configured to store characteristics for said instruments (see Para.0084,

lines 10-16 and also Para.0125, lines 17-19), a second database configured to store

characteristics about a body part to be simulated (Para.0033, lines 1-6 and Para.0124,

lines 5-10), and means for generating control signals relating to an interaction between

said simulated instruments and a surrounding geometry relating to a part of said

simulated body part (Para.0034, lines 3-10 and Para.0125, lines 19-21).

Anderson further discloses, means for simulating an effect of a first instrument

inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each

instrument having properties, being at least one of a natural shape, stiffness, length,

diameter, and radioopacity (Para.0071), said instruction set being configured to

calculate movements of said first instrument propagated to other second instrument

(Para.0084) .

Anderson does not explicitly disclose, means for controlling movements of a

number of serially arranged and interconnected carriages corresponding to movements

of said instruments in said interface device, each carriage comprising members to

receive and lock at least one of the instruments, and members for receiving a

movement from the instrument dummy and generating a force fed back to the

instrument dummy with respect to a simulation characteristic, a detecting arrangement

for detecting the type of the instruments inserted through a interconnecting member,

means to provide the movement of each carriage and regulate the movement by means

of a speed regulator and a distance regulator, a crank block, arranged on a torque

wheel, an outlet, which is provided with a detecting member, configured to detect

presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, means for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device (col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Regarding claim 21, Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above.

Anderson further discloses, said characteristics about a body part to be simulated are obtained through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4).

Regarding claim 22, a computer program for interventional procedure simulation in a system having a control unit and an interface unit (FIG 4), said program comprising a communication instruction set for communication between said control unit a and said interface unit (Para.0114, lines 1-6 and FIG 3), a first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit including an instruction set comprising a second instruction set for

handling and processing input from a user, a third instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an interaction between said simulated nested instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21), and a seventh instruction set for outputting simulation on a visualization member (Para.0097, lines 4-10).

Anderson further discloses, a sixth instruction set for outputting calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity (Para.0071), said sixth instruction set being configured to calculate movements of said first instruction instrument propagated to the second instrument (FIG 5B and Para.0120).

Anderson does not explicitly disclose, a fifth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement

by means of a speed regulator and a distance regulator, a crank block, arranged on a

torque wheel, and an outlet, which is provided with a detecting member, configured to

detect presence of at least one instrument in the carriage, said detecting member being

arranged to detect the thickness of each instrument.

However, Alexander teaches, an instruction set for controlling movements of a

number of serially arranged and interconnected carriages corresponding to movements

of said instruments in said interface device (col.22, lines 5-18 and FIG 16), each

carriage comprising members to receive and lock at least one of the instruments, and

members for receiving a movement from the instrument dummy and generating a force

fed back to the instrument dummy with respect to a simulation characteristic (col.22,

lines 21-39), a detecting arrangement for detecting the type of the instruments inserted

through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to

provide the movement of each carriage and regulate the movement by means of a

speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged

on a torque wheel, and an outlet, which is provided with a detecting member, configured

to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and

col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art

at the time of this invention was made to modify the invention of Anderson in view of

Alexander by incorporating a plurality of carriage assemblies in order to manipulate and

control several nested instruments, such as wire, catheter and sheath assembly so that

the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Regarding claim 23, Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above.

Anderson further discloses, a program storage device readable by a machine and encoding a program of instructions for executing the computer program for interventional procedure simulation according to claim 22 (Para.0006 and Para.0125, lines 1-7).

Regarding claim 24, Anderson discloses the following claimed limitations; a computer readable medium having computer readable program code embodied therein to enable an interventional procedure simulation in a system (Para.0006 and Para.0125, lines 1-7) comprising a control unit and an interface unit (FIG 4), said program

comprising a communication instruction set for communication between said control unit

and said interface unit (Para.0114 and FIG 3), a first instruction set for simulating

handling of a number of simulated nested instruments, independently movable and

rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035),

said control unit further comprising an instruction set, comprising a second instruction

set for handling and processing input from said user, a third instruction set for

controlling said interface (Para.0125 lines 7-14), a first data set comprising

characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second

data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and

Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an

interaction between said simulated nested instruments and a surrounding geometry

relating to a part of said simulated body part (see Para.0033, lines 1-6 and Para.0124,

lines 5-9), a fifth instruction set for calculating an effect of a first instrument inserted into

a second instrument in a nested manner (Para.0035 and Para.0036), each instrument

having properties, being at least one of a natural shape, stiffness, length, diameter and

radioopacity (Para.0071), said fifth instruction set propagated to the second instrument

(FIG 5B and Para.0120), and a sixth instruction set for outputting simulation on a

visualization member (Para.0097, lines 4-10).

Anderson does not explicitly teach, the interface unit having a plurality of

carriages, each carriage comprising members to receive and lock at least one of the

instruments, and members for receiving a movement from the instrument dummy and

generating a force fed back to the instrument dummy with respect to a simulation

characteristic, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, an interface unit having a plurality of carriages, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (see e.g. col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of

Alexander by incorporating a plurality of carriage assemblies in order to manipulate and

control several nested instruments, such as wire, catheter and sheath assembly so that

the user would learn the proper procedural steps to carry out a given medical

procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member

being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect

thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the

time of this invention was made to modify the invention of Anderson in view of

Alexander and further in view of Messner by incorporating a suitable tool calibrator into

the system in order to measure the diameter of the various tools being used before

performing a given medical procedure so that the user would learn the type and size of

the different surgical tools needed for the different medical procedures.

Regarding claim 26, a system for an interventional procedure simulation, said

system including a control unit and an interface unit (FIG 4), the system comprising

means for communication between said control unit and said interface unit for receiving

at least two nested instruments including a first instrument inserted into a second

instrument, used in said interventional procedure (Para.0018 and Para.0035-

Para.0036), means for receiving three-dimensional information on a body part to be

simulated (Para.0021, lines 1-3 and Para.0128, lines 1-4), and means for generating

control signals relating to an interaction between said first and second instruments and

a surrounding geometry relating to a part of said simulated body part (FIG 5B,

Para.0120 and Para.0125, lines 19-21).

Anderson does not explicitly disclose, the control signals being configured to

control movements of a number of serially arranged and interconnected carriages

corresponding to movements of said instruments in said interface device with respect to

movements of said first instrument propagated to the second instrument, each carriage

comprising members to receive and lock at least one of the instruments, and members

for receiving a movement from the instrument dummy and generating a force fed back

to the instrument dummy with respect to a simulation characteristic, a detecting

arrangement for detecting the type of the instruments inserted through a interconnecting

member, means to provide the movement of each carriage and regulate the movement

by means of a speed regulator and a distance regulator, a crank block, arranged on a

torque wheel, and an outlet, which is provided with a detecting member, configured to

detect presence of at least one instrument in the carriage, said detecting member being

arranged to detect the thickness of each instrument.

However, Alexander teaches, control signals configured to control movements of

a number of serially arranged and interconnected carriages corresponding to

movements of said instruments in said interface device with respect to movements of

said first instrument propagated to the second instrument (col.16, lines 54-67 and

col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock

at least one of the instruments, and members for receiving a movement from the

instrument dummy and generating a force fed back to the instrument dummy with

respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for

detecting the type of the instruments inserted through a interconnecting member (col.6,

lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage

and regulate the movement by means of a speed regulator and a distance regulator

(col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged

on a torque wheel, and an outlet, which is provided with a detecting member, configured

to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and

col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art

at the time of this invention was made to modify the invention of Anderson in view of

Alexander by incorporating a plurality of carriage assemblies in order to manipulate and

control several nested instruments, such as wire, catheter and sheath assembly so that

the user would learn the proper procedural steps to carry out a given medical

procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member

being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect

thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the

time of this invention was made to modify the invention of Anderson in view of

Alexander and further in view of Messner by incorporating a suitable tool calibrator into

the system in order to measure the diameter of the various tools being used before

performing a given medical procedure so that the user would learn the type and size of

the different surgical tools needed for the different medical procedures.

Regarding claim 27, Anderson in view of Alexander and further in view of

Messner teaches the claimed limitations as discussed above.

Anderson further discloses, said three-dimensional in formation is obtained

through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4).

●   Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Alexander 6,929,481 in view of Messner 5,987,960.

Regarding claim 29, Alexander discloses the following claimed limitations; a

method of an interventional procedure training (col.5, lines 54-61), using a system

including a control unit and an interface unit (FIG 9, labels 28, 24 and 314), the method

comprising using a real nested interventional procedure tool, including a first tool

inserted into a second tool to be simulated in said interface device (see e.g. FIG 10,

labels 302, 304 and 306), said interface unit including a plurality of carriages, each

carriage comprising members to receive and lock at least one of the instruments, and

members for receiving a movement from the instrument dummy and generating a force

fed back to the instrument dummy with respect to a simulation characteristic (col.22,

lines 21-39), a detecting arrangement for detecting the type of the instruments inserted

through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to

provide the movement of each carriage and regulate the movement by means of a

speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment Alexander further discloses, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (see col.10, lines 57-67 and col.11, lines 1-7), simulating an interaction between said nested first and second tools independently movable and rotatable, and a surrounding geometry relating to a part of said simulated body part, and using said simulation for training a user (col.16, lines 54-67).

Alexander does not explicitly disclose, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Alexander in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Response to Arguments.

6.   Applicant's arguments filled on 02/04/2010 have been fully considered. However, due to the amendment made to the current claims, new grounds of rejection have been established in this current office action; and therefore, Applicant's arguments are now moot.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in

this final office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR

1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filled within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Bruk A. Gebremichael whose telephone number is (571)

270-3079. The examiner can normally be reached on Monday to Friday (7:30AM-

5:00PM) ALT. Friday OFF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, THAI XUAN can be reached on (571) 272-7147. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruk A Gebremichael/
Examiner, Art Unit 3715

/Cameron Saadat/
Primary Examiner, Art Unit 3715